

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/502,403
Filing Date	§ 371(c) Date: June 20, 2005
First Named Inventor	LARA OCHOA, José Manuel Francisco
Art Unit	1611
Examiner Name	Rae, Charlesworth E.
Attorney Docket Number	2099.0090000/PAJ/LMB

Sheet 1 of 3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL1	ABBINK, E.J., <i>et al.</i> , "Vascular effects of glibenclamide vs. glimepiride and metformin in Type 2 diabetic patients," <i>Diabet. Med.</i> 19:136-143, Blackwell Science (February 2002)	
	NPL2	BRESSLER, R., and JOHNSON, D.G., "Pharmacological Regulation of Blood Glucose Levels in Non-Insulin-Dependent Diabetes Mellitus," <i>Arch. Intern. Med.</i> 157:836-848, American Medical Association (1997)	
	NPL3	CEFALU, W.T., <i>et al.</i> , "Insulin Sensitivity is Improved After Glipizide GITS Mono-Therapy and in Combination with Metformin," <i>Diabetologia</i> 39:A231, Springer Verlag (1996)	
	NPL4	CEFALU, W.T., <i>et al.</i> , "Combination Glipizide GITS/Metformin Normalizes Glucose and Improves Insulin Sensitivity in Hyperinsulinemic Moderately Well Controlled NIDDM," <i>Diabetes</i> 45:201A, American Diabetes Association (1996)	
	NPL5	CHARPENTIER, G., <i>et al.</i> , "Improved glycaemic control by addition of glimepiride to metformin monotherapy in Type 2 diabetic patients," <i>Diabet. Med.</i> 18:828-834, Blackwell Science (October 2001)	
	NPL6	CROUSE III, J.R., <i>et al.</i> , "Effects of Combination Glipizide GITS/Metformin Treatment on Oxidizability of LDL in Non-Insulin Dependent Diabetes Mellitus," <i>Circulation</i> 94:1-508, Lippincott Williams & Wilkins (1996)	
	NPL7	DAGOGO-JACK, S., and SANTIAGO, J.V., "Pathophysiology of Type 2 Diabetes and Modes of Action of Therapeutic Interventions," <i>Arch. Intern. Med.</i> 157:1802-1817, American Medical Association (1997)	
	NPL8	DEFRONZO, R.A., "Pharmacologic Therapy for Type 2 Diabetes Mellitus," <i>Ann. Intern. Med.</i> 131:281-303, American College of Physicians (1999)	
	NPL9	DEFRONZO, R.A., <i>et al.</i> , "Efficacy of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>N. Engl. J. Med.</i> 333:541-549, Massachusetts Medical Society (1995)	
	NPL10	GARBER, A.J., <i>et al.</i> , "Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-controlled, Dose-Response Trial," <i>Am. J. Med.</i> 102:491-497, Excerpta Medica, Inc. (1997)	

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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	NPL11	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Eficacia y seguridad de la terapia hipoglucemiante oral combinada de glimepirida más metformina en una sola forma farmacéutica en pacientes con diabetes mellitus tipo 2 y falla secundaria a monoterapia con glibenclámda," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)	√
	NPL12	English Language Translation of GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy and safety of glimepiride plus metformin in a single presentation, as combined therapy, in patients with type 2 diabetes mellitus and secondary failure to glibenclamide, as monotherapy," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)	
	NPL13	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy of glimepiride/metformin combination versus glibenclamide/metformin in patients with uncontrolled type 2 diabetes mellitus," <i>J. Diabetes Complicat.</i> , Elsevier Science Publishing Company, 4 pages, Article in Press, uncorrected proof (September 2008)	
	NPL14	GOMIS, R., <i>et al.</i> , "Appropriate Timing of Glimepiride Administration in Patients with Type 2 Diabetes Mellitus," <i>Endocrine</i> 13:117-121, Endocrine Society (2000)	
	NPL15	HERMANN, L.S., <i>et al.</i> , "Therapeutic Comparison of Metformin and Sulfonylurea, Alone and in Various Combinations," <i>Diabetes Care</i> 17:1100-1109, American Diabetes Association (1994)	
	NPL16	HIGGINBOTHAM, L. and MARTIN, F.I.R., "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics," <i>Med. J. Aust.</i> 2:154-156, Australian Medical Publishing Company Limited (1979)	
	NPL17	HOLSTEIN, A., <i>et al.</i> , "Lower Incidence of Severe Hypoglycaemia in Type 2 Diabetic Patients Treated with Glimepiride Versus Glibenclamide," <i>Diabetologia</i> 43:A 40, Springer Verlag (2000)	
	NPL18	MÜLLER, G., <i>et al.</i> , "Differential interaction of glimepiride and glibenclamide with the β -cell sulfonylurea receptor," <i>Biochim. Biophys. Acta</i> 1191:267-277, Elsevier Pub. Co. (1994)	
	NPL19	ROSENSTOCK, J., <i>et al.</i> , "Glimepiride, a New Once-Daily Sulfonylurea," <i>Diabetes Care</i> 19:1194-1199, American Diabetes Association (1996)	
	NPL20	SATO, J., <i>et al.</i> , "Comparison between effects of glimepiride and glibenclamide on <i>in vivo</i> insulin action," in <i>Proceedings of the Fourth International Symposium on Treatment of Diabetes Mellitus</i> , Nagoya, 26-27 October 1993, Sakamoto, N., <i>et al.</i> , eds., Excerpta Medica, Amsterdam, Netherlands, pp. 341-348 (1994)	
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	NPL21	SCHEEN, A.J., and LEFÈBVRE, P.J., "Oral Antidiabetic Agents. A Guide to Selection," <i>Drugs</i> 55:225-236, ADIS Press (1998)	
	NPL22	SIFTON, D., ed., "Anzemet® Injection," in <i>Physicians Desk Reference, 54th Ed.</i> , Medical Economics Company, Montvale, NJ, pp. 1349-1352 (2000)	
	NPL23	SONNENBERG, G.E., <i>et al.</i> , "Short-Term Comparison of Once- Versus Twice-Daily Administration of Glimepiride in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>Ann. Pharmacother.</i> 31:671-676, Harvey Whitney Books Company (1997)	
	NPL24	VIGNERI, R., <i>et al.</i> , "Treatment of NIDDM Patients with Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide," <i>Diabete. Metab.</i> 17:232-234, Masson (1991)	
	NPL25	International Search Report for International Application No. PCT/MX02/00003, mailed on January 30, 2003, European Patent Office, Rijswijk, Netherlands	
	NPL26	International Preliminary Examination Report for International Application No. PCT/MX02/00003, completed on April 28, 2004, European Patent Office, Munich, Germany	
	NPL27	SHIMPLI, R.D., <i>et al.</i> , "Comparison of effect of metformin in combination with glimepiride and glibenclamide on glycaemic control in patient with type 2 diabetes mellitus," <i>Int. J. PharmTech Res.</i> 1:50-61, Sphinx Knowledge House (January-March 2009)	

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